UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

United States of America ex rel. Scott Louderback,

Relator,

v.

Sunovion Pharmaceuticals, Inc.,

Defendant.

File No. 17-cv-1719 (ECT/LIB)

OPINION AND ORDER

Jeffrey G. Goulder and Michael Vincent, Stinson LLP, Phoenix, AZ, and Sharon Robin Markowitz, Stinson LLP, Minneapolis, MN, for Relator Scott Louderback.

Chad A. Blumenfield, United States Attorney's Office, Minneapolis, MN for United States of America.

John P. Bueker and Sandra H. Masselink, Ropes & Gray LLP, Boston, MA, and Joseph T. Dixon, III and Devin Driscoll, Fredrikson & Byron, P.A., Minneapolis, MN, for Defendant Sunovion Pharmaceuticals, Inc.

Defendant Sunovion Pharmaceuticals manufactured a drug called Brovana. In this *qui tam* lawsuit brought under the federal False Claims Act, Relator Scott Louderback claims that Sunovion caused pharmacies to submit fraudulent claims for Brovana to Medicare. Louderback's fraud theory proceeds in three steps: (1) he alleges that Sunovion paid rebates to pharmacies in exchange for the pharmacies' agreements to arrange for Medicare patients to receive Brovana prescriptions in situations where the patients would have received a different drug or therapy; (2) this rebates-for-prescriptions arrangement violated the federal Anti-Kickback Statute; and (3) by law, a claim that includes items or

services resulting from a violation of the Anti-Kickback Statute in turn violates the False Claims Act.

Sunovion seeks dismissal on several grounds under Rules 12(b)(6) and 9(b). The motion will be granted because the operative Amended Complaint does not contain particular allegations showing that false claims resulted from Sunovion's violations of the Anti-Kickback Statute. The motion will not be granted on other grounds Sunovion raised. These include Sunovion's arguments that the False Claims Act's public-disclosure bar applies, that the alleged practices fall within the Anti-Kickback Statute's "discount" safe harbors, and that the Amended Complaint fails to allege scienter. Each of these issues will be addressed in turn. First, the facts.

I[1]

Relator is a pharmacist, and Defendant is a pharmaceutical company. Louderback is a pharmacist and serves as President of Neighborhood LTC Pharmacy, Inc. Am. Compl. [ECF No. 92] ¶¶ 1, 20, 61. Sunovion is a pharmaceutical company that manufactured a prescription drug called Brovana. *Id.* ¶¶ 1, 37.[2]

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[1] In accordance with the standards governing a Rule 12(b)(6) motion, the facts are drawn from the operative Amended Complaint and materials it necessarily embraces. *See Gorog v. Best Buy Co*., Inc., 760 F.3d 787, 792 (8th Cir. 2014); *Zean v. Fairview Health Servs.*, 858 F.3d 520, 526 (8th Cir. 2017); *see also Greene v. Osborne-Leivian*, No. 19-cv-533 (ECT/TNL), 2021 WL 949754, at *2 n.3 (D. Minn. Mar. 12, 2021), *aff'd*, No. 21-1937, 2021 WL 5121256 (8th Cir. 2021).

[2] Citing publicly available materials, Sunovion represents that in October 2022 it agreed to "divest the U.S. market rights to Brovana to Lupin Ltd." Def.'s Mem. in Supp. [ECF No. 104] at 11 n.3. Page cites throughout this opinion and order are to pagination assigned by CM/ECF appearing in the document's upper right corner, not to a document's original pagination.

Brovana is used to treat chronic obstructive pulmonary disease ("COPD"). Am. Compl. ¶ 1. According to the Amended Complaint, Brovana is a "nebulized long-acting beta-agonist ('LABA') inhalation solution." *Id.* ¶ 37.[3]

The COPD therapy market includes several competitors. The Amended Complaint describes the market for COPD therapies. "Brovana is one of two branded nebulized LABA drugs currently on the market." *Id.* ¶ 38. "The other is Perforomist, which is manufactured by Mylan, Inc." *Id.* ¶ 39. Generic versions of these two drugs have been available since 2022. *Id.* ¶ 40. In addition to these nebulized LABA drugs, non-nebulized LABA therapies and non-LABA therapies are available. *Id.* ¶¶ 41, 43. These non-nebulized and non-LABA therapies are less expensive than Brovana and Perforomist and "are often appropriate for patients [who are] prescribed Brovana." *Id.* ¶¶ 45–46.

Medicare spends a lot on Brovana. Many Medicare beneficiaries are prescribed Brovana, and through Medicare Part B, the United States government spends a lot for these prescriptions. More than ten percent "of the Medicare population has been diagnosed with COPD, and many of these persons are treated with Brovana." *Id.* ¶ 2. In 2010, more than $70 million was spent on Brovana through Medicare, and more than ninety "percent of the spending on Brovana was on Medicare beneficiaries." *Id.*

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[3] "Nebulized" means the drug's liquid form is "[broken] up into a fine spray or vapor." *Stedman's Medical Dictionary* 1283 (28th ed. 2006). A "beta-antagonist" is a medication that treats primarily lung conditions by binding to beta-receptors, in turn relaxing lung muscles to facilitate better breathing. https://my.clevelandclinic.org/health/treatments/24851-beta-agonist (November 26, 2023).

Considering just pharmacies' acquisition cost and Medicare's reimbursement rate, pharmacies would lose money on every Medicare-reimbursed Brovana prescription. Ordinarily, Medicare pays eighty percent of a drug's retail price, leaving the beneficiary to pay the remaining twenty percent. *Id.* ¶ 58. For Brovana, these amounts combined are less than what pharmacies pay to purchase the drug. *Id.* ¶ 59. This is because Medicare has established a maximum price that pharmacies may charge Medicare for Brovana, and Sunovion "sells Brovana at a wholesale price that exceeds" the maximum price established by Medicare. *Id.*

Beginning by at least November 2012, Sunovion addressed this problem by paying chargebacks or rebates to pharmacies that signed on to a "Sunovion Part B Agreement." *Id.* ¶ 68; Ex. B.[4] Three of the Agreement's terms are central to Louderback's claims. (1) The first—which Louderback calls the "dispense-as-written" provision—reads in relevant part as follows:

> **2.3 <u>Prescription Fulfillment</u>:** Except as provided for below, Customer agrees to dispense as written all prescriptions for [Brovana] presented by Medicare Part B Participants. Customer pharmacists shall have the right, at all times during the term of this Agreement, to contact the physician for a Medicare Part B Participant and request that the prescription for [Brovana] be changed to an alternative therapy if, in the exclusive discretion of the Customer pharmacist, such a change is a matter of medical necessity and in the best health interest of the Medicare Part B Participant.

[4] The Part B Agreement may be considered at this motion-to-dismiss stage (without converting the motion to one for summary judgment) because it is attached to the Amended Complaint and its authenticity is not questioned. *Zean*, 858 F.3d at 526–27; *Dittmer Props., L.P. v. F.D.I.C.*, 708 F.3d 1011, 1021 (8th Cir. 2013).

Id. Ex. B § 2.3. (2) The second prohibits "counterdetailing." It reads: "As a condition to receiving discounts pursuant to this Agreement, Customer and its participating facilities and pharmacists must refrain from engaging in any counterdetailing activities directed at [Brovana]." *Id.* Ex. B § 5. According to Louderback, "counterdetailing" means "provid[ing] doctors and patients with positive information about Brovana's competitors." *Id.* ¶ 9; *see also id.* ¶ 76 (defining "counterdetailing" to mean "any effort . . . to control drug costs by educating prescribing physicians on less expensive equivalent or generic alternatives"). (3) The third provision reads: "Customer agrees that Sunovion can identify Customer and utilize any Customer-approved trademark in all materials developed by Sunovion that identify all or a portion of the participants in this program." *Id.* Ex. B § 5.

Louderback claims that these provisions reflect remunerations prohibited by the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1). According to Louderback, though pharmacists ordinarily counsel physicians and patients regarding alternative drugs and therapies, Am. Compl. ¶¶ 47–56, § 2.3's "dispense-as-written" requirement and § 5's counterdetailing prohibition show that, in exchange for a rebate, signatory pharmacies "promise to recommend or arrange for physicians to prescribe, and patients to purchase, Brovana in circumstances in which [the pharmacies] would otherwise recommend or arrange for the prescribing or purchasing of another drug," *id.* ¶ 89. And, Louderback claims, § 5's trademark-use provision amounts to an offer by Sunovion of "free promotional services" (in addition to a rebate) in consideration for signatory pharmacies' promises to promote the prescribing and purchase of Brovana. *Id.* In other words, Louderback alleges that under the Part B Agreement, Sunovion provides something of

value (rebates and promotional services) "to pharmacies in exchange for their agreement to arrange for the prescription (by physicians), dispensing (by the pharmacists) and purchase (by patients and pharmacies) of Brovana in circumstances when, but for the [Part B] Agreement, they would prescribe, dispense, or purchase drugs manufactured by Brovana's competitors." *Id.* ¶ 10.

The Amended Complaint includes some allegations describing Louderback's discovery of the Sunovion Part B Agreement. Louderback, "in his capacity as a pharmacist at Neighborhood LTC Pharmacy Inc., receives prescriptions for Brovana to be provided to Medicare Part B beneficiaries." *Id.* ¶ 61. Knowing that Brovana's cost exceeded Medicare's reimbursement rate, Louderback asked "colleagues about how they were able to provide Brovana to Medicare Part B beneficiaries without suffering a financial loss." *Id.* ¶ 62. One of these colleagues told Louderback about the Part B Agreement and explained that the Agreement was available through Sunovion's website. *Id.* ¶¶ 63–64. In September 2016, Louderback accessed the Part B Agreement through Sunovion's website and executed it on behalf of Neighborhood LTC Pharmacy. *Id.* ¶ 66. The Amended Complaint does not describe precisely what steps Louderback took to access the Sunovion Part B Agreement. It alleges the Agreement was "accessible to people who enter specific identifying information into the website," but it does not allege the nature or content of this identifying information. *Id.* ¶ 94(e). A screen shot of a Sunovion web page through which a person would have accessed the Part B Agreement is attached to the Amended Complaint. *Id.* Ex. A. This page explains that, if a user is a "qualified representative" of an organization, the user need only "click the **ENROLL/SIGN IN** button and create a login

and password" and "complete the required information to request enrollment in the Program." *Id.* The process, the web page explains, takes "approximately 20 minutes." *Id.*

Louderback asserts four theories under the False Claims Act, 31 U.S.C. § 3729, et seq., each derived from alleged violations of the Anti-Kickback Statute. (1) He alleges an "express certification" theory—*i.e.*, that Sunovion "knowingly caused pharmacies to seek reimbursement from the government for Brovana" in contravention of the pharmacies' express certifications that their conduct and claims complied with applicable federal law, including the Anti-Kickback Statute. *See* Am. Compl. ¶¶ 131–38 (Count I). (2) He alleges an "implied certification" theory—*i.e.*, that Sunovion "knowingly caused pharmacies to seek reimbursement from the government for Brovana" without disclosing that the underlying transactions violated the Anti-Kickback Statute. *See id.* ¶¶ 139–45 (Count II). In Louderback's view, "[t]he pharmacies' omission of this information rendered their [Brovana] claims misleading given that industry participants all know of the government's clear practice of not providing reimbursement for sales in any way related to illegal kickback schemes." *Id.* ¶ 143. (3) Louderback alleges a "presentment" theory—*i.e.*, that Sunovion "knowingly caused to be presented thousands of claims including items or services that resulted from [Sunovion's] and pharmacies' violations of the [Anti-Kickback Statute.]" *See id.* ¶¶ 146–55 (Count III). (4) And he alleges a "false record or statement" theory—*i.e.*, that Sunovion caused pharmacies that signed the Part B Agreement to submit claims for Brovana "that contained false records or statements that the claims complied with the [Anti-Kickback Statute]." *See id.* ¶¶ 156–66 (Count IV). On the United States' behalf, Louderback seeks judgment "in an amount not less than $20 billion . . . plus a civil

penalty for each violation of the [False Claims Act] and the [Anti-Kickback Statute]." *Id.* at 31–32, ¶ 1. On his own behalf, Louderback seeks a maximum award of proceeds along with an award of attorneys' fees and costs. *Id.* at 32, ¶¶ 2, 3.[5]

II

A

In reviewing a motion to dismiss for failure to state a claim under Rule 12(b)(6), a court must accept as true all of the factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. *Gorog*, 760 F.3d at 792. Although the factual allegations need not be detailed, they must be sufficient to "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). The complaint must "state a claim to relief that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.*

Considering "matters outside the pleadings" generally transforms a Rule 12(b)(6) motion into one for summary judgment, Fed. R. Civ. P. 12(d), but not when the relevant

[5] There has been considerable delay since Louderback first filed this case in May 2017. *See* ECF No. 1 (showing original filing date). The United States sought enlargements of time to decide whether to intervene on twelve occasions. ECF Nos. 2, 7, 11, 28, 33, 38, 43, 48, 52, 57, 62, 67, 72. The docket does not show that Louderback opposed any of these requests. The United States filed notice of its decision not to intervene in November 2022. ECF No. 77.

materials are "necessarily embraced" by the pleadings. *Zean*, 858 F.3d at 526. "In general, materials embraced by the complaint include documents whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the pleadings." *Id.* (internal quotation marks and citation omitted). Courts "additionally consider matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint whose authenticity is unquestioned." *Id.* (internal quotation marks and citations omitted); *see Miller v. Redwood Toxicology Lab'y, Inc.*, 688 F.3d 928, 931 n.3 (8th Cir. 2012) ("While courts primarily consider the allegations in the complaint in determining whether to grant a Rule 12(b)(6) motion, courts additionally consider 'matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint whose authenticity is unquestioned[,]' without converting the motion into one for summary judgment." (quoting 5B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357 (3d ed. 2004))).

B

The False Claims Act imposes civil liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim [to the Government] for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The Act contains *qui tam* provisions that "allow a private party known as a 'relator' to bring an FCA action on behalf of the Government." *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 26, 29 (2016). These *qui tam* provisions are "designed to benefit both the relator and the

Government. A relator who initiates a meritorious *qui tam* suit receives a percentage of the ultimate damages award, plus attorney's fees and costs." *Id*. A claim under the False Claims Act generally has three elements: (1) the defendant presented or caused to be presented a claim for payment to the government; (2) that claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent. *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1070 (8th Cir. 2016).

In this case, the alleged false or fraudulent claims arise from claimed violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1). Am. Compl. ¶ 27. As relevant here, the Anti-Kickback Statute imposes criminal penalties on a person who

> knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program[.]

42 U.S.C. § 1320a-7b(b)(2)(B). The Statute provides that, in addition to criminal penalties, "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g).

C

1

Begin with Sunovion's argument that Louderback's claims should be dismissed under the False Claims Act's public-disclosure bar. "At the same time that the [False Claims Act] encourages whistleblowers, it discourages 'opportunistic' plaintiffs who

'merely feed off a previous disclosure of fraud.'" *United States v. CSL Behring, L.L.C.*, 855 F.3d 935, 941 (8th Cir. 2017) (quoting *United States v. Walgreen Co.*, 846 F.3d 879, 880 (6th Cir. 2017)). To that end, the Act's public-disclosure bar provides:

> (A) The court shall dismiss an action or claim under this section . . . if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
>
> > (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> >
> > (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> >
> > (iii) from the news media,
> >
> > > unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). "Dismissal under the public disclosure bar is . . . required if (1) the defendant has shown public disclosure under § 3730(e)(4)(A), and (2) the relator does not fit § 3730(e)(4)(B)'s definition of 'original source.'" *United States ex rel. Paulos v. Stryker Corp.*, 762 F.3d 688, 692 (8th Cir. 2014).

2

The interplay between Rule 12(b)(6) and the public-disclosure bar deserves discussion. "Prior to 2010, 31 U.S.C. § 3730(e)(4) removed a court's subject matter jurisdiction where the allegations and transactions of an FCA action previously had been publicly disclosed." *United States ex rel. Ambrosecchia v. Paddock Lab'ys, LLC*, 855 F.3d 949, 953 (8th Cir. 2017); *see United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 827 (8th Cir. 2013) (applying pre-2010 jurisdictional bar to case filed pre-amendment).

The 2010 amendments applicable here removed the jurisdictional reference, prompting questions regarding whether the public disclosure bar is an affirmative defense and whether the bar's presence is appropriate for resolution under Rule 12(b)(6).

The Eighth Circuit has not answered the affirmative-defense question. "The federal courts of appeals that have confronted the issue have unanimously held that the 2010 amendments transformed the public disclosure bar from a jurisdictional bar to an affirmative defense." *United States ex rel. Reed v. KeyPoint Gov't Sols.*, 923 F.3d 729, 737 n.1 (10th Cir. 2019) (quotation omitted) (citing cases); *see United States ex rel. Grant v. Zorn*, No. 4:18-cv-00095-SMR-SBJ, 2021 WL 4145724, at *4 n.3 (S.D. Iowa Mar. 8, 2021) (same). The Eighth Circuit has said "that the amended public disclosure bar is appropriately resolved on a motion to dismiss, even assuming that it no longer poses a jurisdictional question." *Ambrosecchia*, 855 F.3d at 953 (citing *Paulos*, 762 F.3d at 696; *see United States ex rel. Kraxberger v. Kansas City Power and Light Co.*, 756 F.3d 1075, 1078–80 (8th Cir. 2014) (affirming Rule 12(b)(6) dismissal of claims based on public disclosure bar).

Regardless, in many (perhaps a great majority of) cases, the affirmative-defense question will be academic. Though an affirmative defense does not subject a complaint to dismissal unless the complaint or materials that appropriately may be considered on a Rule 12(b)(6) motion establish the defense beyond dispute, *Roiger v. Veterans Affs. Health Care Sys.*, No. 18-cv-00591 (ECT/TNL), 2019 WL 572655, at *7 (D. Minn. Feb. 12, 2019) (citing 5B Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure: Civil* § 1357 (3d ed. & Nov. 2018 Update)), a document relevant

to the public disclosure bar will often fall in a category of materials that are fair game for consideration at the motion-to-dismiss stage, *see Ambrosecchia*, 855 F.3d at 953–54. We have that here. The public disclosures on which Sunovion bases this aspect of its motion appear in exhibits attached to the Amended Complaint, and no party questions the exhibits' authenticity. The bottom line, then, is that there is nothing procedurally improper about adjudicating the public-disclosure bar here under Rule 12(b)(6).

3

The disputed public-disclosure issue here concerns the "news media" category. Sunovion says that Louderback's Amended Complaint should be dismissed because "the [Part B] Agreement was at all relevant times available and accessible on Sunovion's website" and courts have construed the "news media" public-disclosure category to include information on publicly available websites. *See* Def.'s Mem. in Supp. at 14–18; Def.'s Reply Mem. [ECF No. 118] at 8–11. Louderback disagrees. He argues that Sunovion's "website is not the 'news media,'" and he seeks to distinguish the cases Sunovion cites in support of its motion. *See* Relator's Mem. in Opp'n [ECF No. 117] at 11–14. The answer to this question is not obvious.

a

Binding precedents are in short supply. The Supreme Court has not addressed the "news media" category, other than to observe that "[t]he 'news media' referenced in [31 U.S.C. § 3730(e)(4)(A)(iii)] plainly have a broader sweep." *Graham Cnty. Soil and Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 290 (2010). The court included this observation to show that the False Claims Act's news-media category

included more than just federally funded or "private outlets [that] have a national focus." *Id.* This, in turn, supported the court's conclusion that the term "administrative" in § 3730(e)(4)(A)(i) "encompasses disclosures made in state and local sources as well as federal sources." *Id.* at 283. The court repeated the "broader sweep" observation in *Schindler Elevator Corp. v. United States ex rel. Kirk*, though again this case did not require the court to apply the news-media category. 563 U.S. 401, 408 (2011). The notion that the False Claims Act's public-disclosure bar has a "generally broad scope" holds obvious importance, *id.*, but it does not answer whether the news-media category includes information on publicly available websites.

Our Eighth Circuit Court of Appeals has applied the public-disclosure bar's "news media" category just once—in *Kraxberger*, 756 F.3d at 1078–79. *Kraxberger*'s facts were not particularly complicated, at least to the extent they are relevant here. The relator, Kraxberger, claimed that the defendant, Kansas City Power and Light Co., "fraudulently induced the General Services Administration ['GSA'] to install an all-electric heating-and-cooling system" in a federal building. *Id.* at 1077. Kraxberger alleged that Kansas City Power's project bid assumed a 7% future rate increase. *Id.* at 1078. Kansas City Power knew this assumption was false, Kraxberger alleged, because the month before submitting the bid it had proposed an 11.5% future rate increase to its regulator, the Missouri Public Service Commission. *Id.* Kansas City Power's support of the 11.5% rate increase was the subject of hearing testimony in 2006 available through the Commission's website. *Id.* After GSA accepted Kansas City Power's bid, the Commission refused to except the project from the 11.5% increase. *Id.* At a later hearing in 2008, a Kansas City Power

manager testified that the GSA's acceptance of the bid was based on the 7% rate in the bid. *Id.* This testimony too was available on the Commission's website. *Id.* Kraxberger filed the case in 2011. *Id.*

The Eighth Circuit concluded that "[t]he 2006 and 2008 hearing testimony, publicly available on the website of the [Commission], qualify as disclosure through the news media." *Id.* at 1079. The court reached this conclusion on essentially three grounds. (1) It noted that, although the False Claims Act does not define "news media," "the Supreme Court has acknowledged the term has a 'broad sweep.'" *Id.* (quoting *Schindler*, 563 U.S. at 408). (2) It determined that the Commission "functions as a news organization for public utilities and consumers in Missouri." *Id.* As the court explained, the Commission "maintains a 'media center' hosting press releases, webcasts of public meetings, and [a magazine] (reporting news and promotions related to public utilities)." *Id.* As authority for this determination, the court cited a Missouri statute that required the Commission to "publish[] in pamphlet, book, or electronic form" matters regarding "the field of public utilities regulation that may . . . be of interest to the public." *Id.* (citing Mo. Rev. Stat. § 386.180). The court also cited for comparison's sake a section of the Administrative Procedure Act defining "a representative of the news media" for purposes of agency regulations governing document-duplication fee schedules. *See id.* (quoting 5 U.S.C. § 552(a)(4)(A)(ii)). (3) The court cited two cases for the proposition that the term "news media" as used in the False Claims Act includes information on "readily accessible" websites. *Id.* (citing *United States ex rel. Doe v. Staples, Inc.*, 932 F. Supp. 2d 34, 40

(D.D.C. 2013), and *United States ex rel. Osheroff v. HealthSpring, Inc.*, 938 F. Supp. 2d 724, 732–33 (M.D. Tenn. 2013)).

b

Notwithstanding the scarcity of precedents that are binding here, many federal courts have addressed the public disclosure bar's "news media" category. A thorough review of these many non-binding decisions shows they fall into either of two broad categories.

i

Numerous courts have held—consistent with the *Staples, Inc.* and *HealthSpring, Inc.* decisions the Eighth Circuit cited in *Kraxberger*—that information disclosed on a readily accessible, publicly available website generally qualifies as "news media" for purposes of the public-disclosure bar regardless of whether the website belongs to a traditional news-gathering or comparable organization.

An example of this category is *United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805 (11th Cir. 2015). There, the relator, Osheroff, alleged that Miami-area medical clinics provided patients with "a variety of free services . . . including transportation, meals, spa and salon services, and entertainment." *Id.* at 808. Osheroff alleged that these services were provided "without regard for medical purpose or financial need" and thus amounted to inducements and remunerations prohibited by the Anti-Kickback Statute. *Id.* Osheroff obtained information supporting these allegations through interviews, newspaper articles, and "information from the clinics' websites." *Id.* After observing that the newspaper articles plainly qualified as news media, the court found that newspaper advertisements

and the clinics' websites also qualified. *Id.* at 813–14. As legal support, the court cited the Supreme Court's statement that "news media" "has 'a broad[] sweep.'" *Id.* at 813 (quoting *Graham Cnty.*, 559 U.S. at 290). The court also cited several district court decisions holding "that the term includes publicly available websites." *Id.* From these authorities, the court reasoned:

> Because the term "news media" has a broad sweep, we conclude that the newspaper advertisements and the clinics' publicly available websites, which are intended to disseminate information about the clinics' programs, qualify as news media for purposes of the public disclosure provision. Like the *Miami Herald* articles, these sources also discuss the clinics' free services and programs. An advertisement in the *Miami Herald* stated that one of the Humana defendants, CarePlus, provided health plans with benefits including "$0 for unlimited transportation." In addition, CAC's website, in the version attached to the amended complaint, disclosed "free transportation services and a variety of educational programs and group activities,""[c]omplimentary lunch . . . on a daily basis," and "massage, [and] monthly birthday parties." [Another clinic] website, in the version attached to the amended complaint, disclosed "unlimited transportation services," spa centers, social activities, and beauty salons.

Id. at 813–14 (internal citations omitted).

Numerous other cases reach this same result. *See, e.g.*, *United States ex rel. Jacobs v. JP Morgan Chase Bank, N.A.*, No. 20-20543-CIV-CANNON/Otazo-Reyes, 2022 WL 573663, at *5–6 (S.D. Fla. Feb. 25, 2022), *appeal filed*, No. 22-10963 (11th Cir. Mar. 28, 2022); *United States ex rel. Beck v. St. Joseph Health Sys.*, No. 5:17-CV-052-C, 2021 WL 7084164, at *3 (N.D. Tex. Nov. 30, 2021); *United States ex rel. Cherwenka v. Fastenal Co.*, No. 14-cv-187 (PAM/BRT), 2018 WL 2069026, at *7 (D. Minn. May 3, 2018); *United States ex rel. Hong v. Newport Sensors, Inc.*, SACV 13-1164-JLS (JPRx), 2016 WL

8929246, at *4–5 (C.D. Cal. May 19, 2016); *United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 2:12cv1600, 2016 WL 1255294 at *16–17 (W.D. Pa. Mar. 31, 2016), *vacated on other grounds*, 728 F. App'x 101, 104–05 (3d Cir. 2018); *United States ex rel. Shea v. Verizon Commc'ns, Inc.*, 160 F. Supp. 3d 16, 25 (D.D.C. 2015); *United States ex rel. Green v. Serv. Cont. Educ. & Training Tr. Fund*, 843 F. Supp. 2d 20, 32 (D.D.C. 2012); *United States ex rel. Repko v. Guthrie Clinic, P.C.*, No. 3:04cv1556, 2011 WL 3875987, at *7–8 (M.D. Pa. Sept. 1, 2011); *see also United States ex rel. Berkley v. Ocean State, LLC*, C.A. No. 20-538-JJM-PAS, 2023 WL 3203641, at *3–4 (D.R.I. May 2, 2023) (rejecting "multilayered analysis of what constitutes 'news media'" and finding "that there is no requirement that the website must curate the information or exercise editorial judgment" to be considered "news media").

ii

A number of courts demand more and find that information available through a publicly accessible website qualifies as "news media" if the disclosure occurred through a source resembling a traditional news media organization and concerned information that qualified as newsworthy.

An example of this category is *United States ex rel. Integra Med Analytics LLC v. Providence Health and Servs.*, No. CV 17-1694 PSG (SSx), 2019 WL 3282619 (C.D. Cal. July 16, 2019), *rev'd on other grounds*, 854 F. App'x 840 (9th Cir. 2021). In this case, the relator alleged that a large health system and its affiliates were guilty of "upcoding"—*i.e.*, that they submitted Medicare claims based on unsupported diagnosis codes that resulted in unjustifiably higher reimbursement. *Id.* at *1–3. Some information supporting the claim

came from websites operated by the health system, its affiliates, or third parties. *Id.* at *9. The court acknowledged that there "appears to be a general consensus in the federal courts that the news media provision of the public disclosure bar encompasses information from at least some types of online sources that might not traditionally be described as news media." *Id.* at *13. The court criticized these decisions for their lack of analysis and failure to define "news media" (and thereby ground their interpretation in statutory text). *Id.* Relying on dictionary definitions of "news" and "medium," the court determined that "news media" for the public-disclosure bar's purposes means: "information about recent events or that would otherwise commonly be found in a newspaper, news broadcast, or other news source." *Id.* at *11. To determine whether information fit this definition, the court identified five relevant considerations. *Id.* at *14–15. These included: (1) "the extent to which the information typically conveyed by a source would be considered newsworthy"; (2) the extent to which the entity "curates information—in contrast to an entity that simply publishes information about itself"; (3) whether the source "intend[s] to disseminate the information widely, as opposed to only to a few individuals"; (4) the extent to which the source "functions" like a traditional news outlet like a newspaper or radio or television station; and (5) most importantly, "whether the source in question . . . could reasonably be described as 'news media' as at least some people would [use] that term in everyday speech." *Id.* The court determined that it was not able to apply these factors to the relator's website sources because the record did not include information regarding the "specific nature of each source." *Id.* at *15–16.

Other cases have applied these same or similar considerations to determine whether information from a publicly available website is "news media." *See, e.g.*, *United States ex rel. Kuriyan v. Molina Healthcare of N.M., Inc.*, No. 16-cv-1148 JB-KK, 2023 WL 5526373, at *11–12 (D.N.M. Aug. 28, 2023); *United States ex rel. MC2 Sabtech Holdings, Inc. v. GET Eng'g Corp.*, 580 F. Supp. 3d 876, 889–90 (S.D. Cal. 2022), *vacated on other grounds*, No. 3:19-cv-01249-RSH-AGS, 2022 WL 19001954 (S.D. Cal. Dec. 22, 2022); *Silbersher v. Allergan Inc.*, 506 F. Supp. 3d 772, 805–07 (N.D. Cal. 2020), *rev'd on other grounds*, 46 F.4th 991 (9th Cir. 2022); *United States ex rel. Gharibian v. Valley Campus Pharmacy, Inc.*, No. 2:16-cv-04777-MCS-PLA, 2021 WL 4816648, at *8 (C.D. Cal. June 23, 2021); *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, No. 13–2983, 2014 WL 4375638, at *9–11 (E.D. Pa. Sept. 4, 2014).

c

The better conclusion here is that the information disclosed on Sunovion's website—the screen shot attached as Exhibit A to the Amended Complaint and the Part B Agreement attached as Exhibit B—do not fall within the "news media" category of the False Claims Act's public-disclosure bar. This is so for several reasons.

(i) I read *Kraxberger* to endorse a broad understanding of "news media," but not so broad as to encompass all information on publicly available websites. The Eighth Circuit's analysis was more specific. The court found that the Missouri Public Service Commission functioned as a news organization by virtue of its actions—that is, because it acted like a traditional news organization in several respects—and by virtue of its statutory charge to curate and publish information that the Commission, in the exercise of discretion,

determined was newsworthy. *Kraxberger*, 756 F.3d at 1079. If the ready accessibility of information on the Commission's website were alone enough, the court's discussion of the Commission's news-organization-like activities and statutory charge would have been unnecessary. I do not understand these aspects of the opinion to have been *obiter dictum*. *Kraxberger*'s citation to the APA's "news media representative" definition supports this understanding. *Id.* That definition includes information-gathering, editorial, and distribution activities. *Id.* Again, if the court's holding were that news media included information on publicly available websites, it would have been unnecessary to compare the Commission's role to these activities. It is true that the court cited two district court cases—*Staples* and *HealthSpring*—for the proposition that information on readily accessible websites constitutes public disclosure. *Id.* Considered against the court's discussion of the Commission's news gathering activities and statutory charge, I think these citations are better understood—not as an endorsement of the notion that everything on a public, readily accessible website is "news media"—but that information within the news-media category does not lose its news-media character by appearing on a website.

(ii) The False Claims Act's plain text supports this conclusion and reading of *Kraxberger*. Not every public disclosure bars a *qui tam* suit. To operate as a bar, a disclosure must fall within one of the FCA's identified categories, and the only category at issue here is "news media." 31 U.S.C. § 3730(e)(4)(A). Without more, a rule that "information on readily accessible public websites constitutes public disclosure," *HealthSpring, Inc.*, 938 F. Supp. 2d at 733, would mean that mere public disclosure would trigger the bar. It is difficult to identify a limiting principle, much more a limiting principle

that aligns with a notion of "news media." That conclusion would be at odds with the Act's plain structure and text. Dictionary definitions dating to the news-media category's 1986 enactment support this understanding. *See Graham Cnty.*, 559 U.S. at 294 (noting the provision's 1986 enactment). The term "news" was defined as "a report of recent events," "material reported in a newspaper or news periodical or on a newscast," and "matter that is newsworthy." Webster's Ninth New Collegiate Dictionary 796 (1984). The same source noted the term "media" was used popularly "in references to the agencies of mass communication." *Id.* 737; *see also id.* at 738 (defining "medium" as "a channel or system of communication, information, or entertainment"). Not all available information was "news media" in 1986, and the same principle should hold today.

(iii) Factually, there is no evidence on this record suggesting that Sunovion functioned as a news organization in a manner akin to the Missouri Public Service Commission in *Kraxberger* when it published information regarding the Brovana Medicare Part B Program or the Medicare Part B Agreement on its website. It is at least plausible that the website and Part B Agreement were merely customer-directed communications. In this way, the information was functionally equivalent to an organization's terms of use or other contractual information made available through a website or other medium for customers to read. It is no doubt true that a hypothetical Sunovion press release announcing the Brovana Medicare Part B Program might have included the same information as was available on the Sunovion website, or that such a press release might have parroted

provisions in the Part B Agreement. But there is no indication here that the website or Part B Agreement ever functioned in this way.[6]

D

The next issue is whether the Anti-Kickback Statute's "discount" exception or associated "discount" regulatory safe harbor requires dismissal of Louderback's Amended Complaint. Sunovion argues both the statute and regulation require dismissal. Louderback disagrees on procedural and substantive grounds.

The Anti-Kickback Statute says that its prohibitions regarding illegal remunerations "shall not apply to . . . a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(A). The relevant regulations exempt "discount[s]," 42 C.F.R. § 1001.952(h), defined as "a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction," *id.* § 1001.952(h)(5), provided (as relevant here) that "[1] the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; [2] inform the buyer . . . of its obligations to report such discount [to the Government] and to provide information upon request [to the Government]; and

[6] Because I conclude that the Part B Agreement and other cited information available on Sunovion's website are not "news media," it is not necessary to determine whether Louderback is an "original source." 31 U.S.C. § 3730(e)(4)(B).

[3] refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph," *id.* § 1001.952(h)(2)(iii)(B).

"Courts generally treat the AKS's safe-harbor provisions as affirmative defenses." *In re EpiPen Direct Purchaser Litig.*, No. 20-cv-0827 (ECT/TNL), 2021 WL 147166, at *15 (D. Minn. Jan. 15, 2021) (citing *United States v. Yielding*, 657 F.3d 688, 700 (8th Cir. 2011); *United States v. Job*, 387 F. App'x 445, 455–56 (5th Cir. 2010); *United States v. Norton*, 17 F. App'x 98, 102 (4th Cir. 2001); *United States v. Medoc Health Servs. LLC*, 470 F. Supp. 3d 638, 651 (N.D. Tex. 2020)). Thus, Louderback's Amended Complaint fails if it is self-defeating on this point and establishes the defense beyond dispute. *Roiger*, 2019 WL 572655, at *7.

Sunovion argues that the Part B Agreement alone meets all elements of the Anti-Kickback Statute's discount exception and the regulatory safe harbor, but this contention is not persuasive at the motion-to-dismiss stage. (1) Though Sunovion seems to accept that the statutory and regulatory safe harbors are affirmative defenses, Def.'s Mem. in Supp. at 20, it faults Louderback for "not alleg[ing] that CMS's reimbursement rate for Brovana failed to appropriately reflect the reduced price" described in the Part B Agreement, *id.* at 22. If the statutory and regulatory "discount" safe harbors are affirmative defenses, then it wasn't Louderback's job to allege facts negating them—or any element of them—in the Amended Complaint. (2) It is true, as Sunovion points out, that the Part B Agreement includes terms directed at requiring or facilitating compliance with the Anti-Kickback Statute, including elements of the statutory and regulatory "discount" safe harbors. *See* Am. Compl. Ex. B §§ 1.9, 2.4(c), (e), (g). Accepting that the Part B Agreement's terms

establish what in fact transpired in the Brovana-related transactions between Sunovion, signatories to the Part B Agreement, and Medicare relative to the discount safe harbors would require drawing factual inferences in Sunovion's favor. Rule 12(b)(6) forbids that.

E

The Anti-Kickback Statute includes a scienter element—*i.e.*, the assertedly illegal remuneration must have been undertaken "knowingly and willfully." 42 U.S.C. § 1320a-7b(b)(2). Sunovion argues that the Amended Complaint fails to allege facts plausibly showing this essential element's presence. This argument takes several specific forms. According to Sunovion, "no reasonable person" would have any reason to doubt whether the Part B Agreement fell within the statutory and regulatory discount safe harbors discussed in the preceding section. Def.'s Mem. in Supp. at 29. This is because, as Sunovion describes the situation, no "existing agency guidance" or other legal authority casts doubt on the Part B Agreement's legality. *See id.* at 30–31. Sunovion argues that the Amended Complaint omits factual allegations showing Sunovion's subjective knowledge that the Agreement was unlawful. *Id.* at 31–32. And Sunovion suggests that the Part B Agreement's availability on its website "for all to see" establishes that it did not act knowingly and willfully. *Id.* at 32.

These arguments are not persuasive. For purposes of a False Claims Act case, whether a hypothetical person might have reasonably concluded that the Part B Agreement fell within a discount safe harbor is not dispositive of the scienter question. *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749 (2023) ("The FCA's scienter element refers to [a defendant's] knowledge and subjective beliefs—not to what an objectively

reasonable person may have known or believed."). Regardless, Sunovion's assertions regarding the absence of existing agency guidance are contradicted at least by the many authorities cited in the United States' Statement of Interest. *See* ECF No. 120 at 1–6. The Amended Complaint includes allegations plausibly showing scienter. *See* Am. Compl. ¶¶ 91–97. Accepting the inference that the Part B Agreement's public availability defeats scienter would require drawing a significant factual inference in Sunovion's favor at the motion-to-dismiss stage. I cannot do that.

F

"Because the FCA is an anti-fraud statute, complaints alleging violations of the FCA must comply with Rule 9(b)." *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006). "To satisfy the particularity requirement of Rule 9(b), the complaint must plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." *Id.* "The claim must identify who, what, where, when, and how." *United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003). "A relator can meet the Rule 9(b) requirements by pleading (1) 'representative examples of the false claims,' or (2) the 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *United States ex rel. Strubbe v. Crawford Cnty. Mem'l Hosp.*, 915 F.3d 1158, 1163 (8th Cir. 2019) (quoting *United States ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 918 (8th Cir. 2014)); *see also United States ex rel. Benaissa v. Trinity Health*, 963 F.3d 733, 739–40

(8th Cir. 2020); *United States ex rel. Dunn v. N. Mem'l Health Care*, 739 F.3d 417, 420 (8th Cir. 2014); *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822 (8th Cir. 2009); *Joshi*, 441 F.3d at 557.

While Rule 9(b) requires particularity in pleading, "a complaint need not be filled with precise detail." *Moua v. Jani-King of Minn., Inc.*, 613 F. Supp. 2d 1103, 1110 (D. Minn. 2009). Rather, "Rule 9(b) is to be read in the context of the general principles of the Federal Rules, the purpose of which is to simplify pleading. Thus, the particularity required by Rule 9(b) is intended to enable the defendant to respond specifically and quickly to the potentially damaging allegations." *Costner*, 317 F.3d at 888. "The level of particularity required depends on the nature of a case," *E-Shops Corp. v. U.S. Bank Nat'l Ass'n*, 678 F.3d 659, 663 (8th Cir. 2012), and to determine whether a party has satisfied Rule 9(b), courts look to "the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading," *Payne v. United States*, 247 F.2d 481, 486 (8th Cir. 1957) (citation omitted).

Sunovion argues that the Amended Complaint does not sufficiently plead causation—*i.e.*, that, but for the assertedly illegal terms in the Part B Agreement, pharmacies would have prescribed a different therapy to their patients. For reasons about to be discussed, this is persuasive.

When a relator (or the United States) seeks to show that a claim is "false or fraudulent" under the False Claims Act because the claim "includes items or services resulting from a violation of" the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(g), the

relator must show a "but-for causal [relationship] between an anti-kickback violation and the 'items or services' included in the claim." *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 831 (8th Cir. 2022). A relator, in other words, must show "that the defendant[] would not have included particular 'items or services' absent the illegal kickbacks." *Id.* at 835; *see United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052–53 (6th Cir. 2023) (same); *see also United States v. Regeneron Pharm., Inc.*, No. 20-cv-11217-FDS, 2023 WL 6296293, at *7–11 (D. Mass. Sept. 27, 2023) (same).

To frame the rule in the context of this case's procedural posture and liability theory, Louderback must allege facts plausibly showing that signatory pharmacies would not have included Brovana prescriptions on Medicare claims absent the remunerations reflected in the Part B Agreement, and he must allege these facts with the particularity Rule 9(b) requires. Every one of Louderback's False Claims Act theories derives from alleged violations of the Anti-Kickback Statute. *See* Am. Compl. ¶¶ 134, 136–37 (Count I); 142–44 (Count II); 148–54 (Count III); 158–65 (Count IV).

The Amended Complaint does not meet these standards. The pleading's explicit references to but-for causation are quite general, even conclusory. The Amended Complaint alleges, for example, that pharmacies arranged for the prescription of Brovana to Medicare patients "in circumstances when, but for the [Part B] Agreement," a competing drug or therapy would have been prescribed. Am. Compl. ¶ 10; *see also id.* ¶ 88 (alleging that the Part B Agreements "restrictions ultimately mean that participating pharmacies recommend purchasing and prescribing Brovana in situations where, but for the [Part B] Agreement, they would recommend purchasing or prescribing an alternative drug"); ¶ 150

("Every pharmacy that entered into the [Part B] Agreement made claims for reimbursement for Brovana that 'resulted from' Defendant's violations of the AKS—*i.e.*, claims for reimbursement for Brovana that the pharmacy would not have made in the absence of the illegal kickbacks."). The Amended Complaint identifies no representative examples of Brovana Medicare claims a signatory pharmacy would not have submitted for payment absent the remunerations reflected in the Part B Agreement. It is true that the Amended Complaint includes a chart identifying eleven Brovana claims submitted by a signatory pharmacy. *Id.* ¶ 110. But the chart does not purport to show a but-for causal connection between these claims and the Part B Agreement; the Amended Complaint alleges only that these claims were submitted "while the [Part B] Agreement was in effect." *Id.*

Louderback and the United States argue that the Amended Complaint need not show but-for causation at all. *See* Relator's Mem. in Opp. at 33–34; United States' Statement of Interest at 7–12. As I understand it, their shared argument is that, notwithstanding *Cairns*, a False Claims Act relator remains free to prove that a claim is false or fraudulent by showing merely that the claim violates a material reimbursement condition, and the Anti-Kickback Statute's remuneration prohibitions are material reimbursement conditions. Louderback and the United States argue that *Cairns* left the door open to this theory. They rely on the following passage from *Cairns* to support this contention:

> Our ruling today is narrow. We do not suggest that every case arising under the False Claims Act requires a showing of but-for causation. Rather, when a plaintiff seeks to establish falsity or fraud through the 2010 amendment, it must prove that a defendant would not have included particular "items or services" but for the illegal kickbacks. 42 U.S.C. § 1320a-7b(g). Here, given that the government's sole theory at trial

> hinged on the 2010 amendment, the district court never instructed the jury on but-for causation, and there is no telling what the jury would have done if it had, we remand for a new trial.

42 F.4th at 836–37. Louderback and the United States imply that Louderback's claims in this case, or at least some of them, are independent of "the 2010 amendment"—*i.e.*, the current version of 42 U.S.C. § 1320a-7b(g). They also rely on a decision from this District accepting this argument, *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, No. 13-cv-3003 (WMW/DTS), 2023 WL 36174, at *1–3 (D. Minn. Jan. 4, 2023).

This argument is not persuasive. It rests on a flawed interpretation of 42 U.S.C. § 1320a-7b(g). The statute is better construed to mean that a False Claims Act case premised on an underlying Anti-Kickback Statute violation must satisfy § 1320a-7b(g)'s requirements. In other words, there is no such thing as a False Claims Act case premised on an Anti-Kickback violation that need not go through § 1320a-7b(g). *See Martin*, 63 F.4th at 1052 ("When it comes to violations of the Anti-Kickback Statute, only submitted claims 'resulting from' the violation are covered by the False Claims Act."). If § 1320a-7b(g) didn't mean that and left the door open to a "material violations" theory, the statute would have little practical effect. What Anti-Kickback/False Claims Act relator would go to the trouble of attempting to allege a claim under § 1320a-7b(g) and meet its but-for causation standard when a less demanding path is available? The argument also rests on a mistaken understanding of *Cairns*. The "narrowness" of the court's holding arose from the fact that the claims in that case depended exclusively—as the claims here depend exclusively—on Anti-Kickback violations. 42 F.4th at 836–37. Not every False

Claims Act case depends on Anti-Kickback violations. Had the Government advanced some other theory in *Cairns* independent of the Anti-Kickback Statute—say, for example, an "upcoding" theory or a theory that claimed services were not rendered—then a showing of but-for causation may not have been required. *Id.* at 836. And it seems reasonable to expect that, had the *Cairns* court meant to adopt the position Louderback and the Government advance here, the court would have said so, perhaps by explaining: "We do not suggest that every case arising under the False Claims Act *through the Anti-Kickback Statute* requires a showing of but-for causation." The opinion gives no reason to think the court adopted such a rule.

The failure to allege facts plausibly showing but-for causation with the particularity required by Rule 9(b) warrants the Amended Complaint's dismissal. A dismissal with prejudice is typically appropriate when a plaintiff has shown "persistent pleading failures" despite one or more opportunities to amend, *Milliman v. Cnty. of Stearns*, No. 13-cv-136 (DWF/LIB), 2013 WL 5426049, at *16 (D. Minn. Sept. 26, 2013); *see Reinholdson v. Minnesota*, No. 01-cv-1650 (RHK/JMM), 2002 WL 32658480, at *5 (D. Minn. Nov. 21, 2002) (adopting report and recommendation), or when the record makes clear that any amendment would be futile, *see Paisley Park Enters. v. Boxill*, 361 F. Supp. 3d 869, 880 n.7 (D. Minn. 2019). On the other hand, when claims "might conceivably be repleaded with success," dismissal without prejudice is ordinarily justified. *Washington v. Craane*, No. 18-cv-1464 (DWF/TNL), 2019 WL 2147062, at *5 (D. Minn. Apr. 18, 2019), *report and recommendation adopted*, 2019 WL 2142499 (D. Minn. May 16, 2019). Louderback's

failure to plead but-for causation in line with Rule 9(b) is better understood as falling in the latter category.[7]

ORDER

Therefore, based on the foregoing, and on all the files, records, and proceedings herein, **IT IS ORDERED THAT**:

1. Defendant Sunovion Pharmaceutical, Inc.'s Motion to Dismiss [ECF No. 103] is **GRANTED** as follows:

   a. The Amended Complaint is **DISMISSED WITH PREJUDICE** to the extent it alleges that promotional services provided by Sunovion were remunerations prohibited under the Anti-Kickback Statute.

   b. The Amended Complaint is otherwise **DISMISSED WITHOUT PREJUDICE** on the ground that Relator Scott Louderback has failed to plead his claims with the particularity required by Federal Rule of Civil Procedure 9(b), as described above.

[7] In *Martin*, the court held that "remuneration" for the Anti-Kickback Statute's purposes "covers just payments and other transfers of value" and not "any act that may be valuable to another." 63 F.4th at 1048–52. Sunovion cited *Martin* in its opening brief for this proposition and argued that *Martin*'s interpretation doomed Louderback's claims to the extent they rest on allegations that Sunovion provided "promotional services." Def.'s Mem. in Supp. at 28. Louderback did not respond to this argument. *See* Relator's Mem. in Opp'n at 25–26. Therefore, regardless of whether *Martin* is correct, Louderback has waived the issue. *See Rivera v. Bank of Am., N.A.*, 993 F.3d 1046, 1051 (8th Cir. 2021).

2. On or before January 12, 2024, Relator may file a second amended complaint. If no second amended complaint is filed by that deadline, judgment will be entered dismissing the Amended Complaint with prejudice for the reasons described in this Order.

Dated: November 27, 2023

s/ Eric C. Tostrud
Eric C. Tostrud
United States District Court